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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,569

Applicant(s)

HASING ET AL.

Examiner

IVES WU

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- (1). **Claims 10-12, 14-19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 recites the limitation "wherein degassing from the solvent is done following solution of the component or the hyperpolarized atomic nuclei" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is rejected due to its dependence upon a rejected base claim.

Claim 12 recites the limitation "steps for dissolving and degassing" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "degassing an enriched component" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 15-19 are rejected due to their dependence upon a rejected base claim..

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

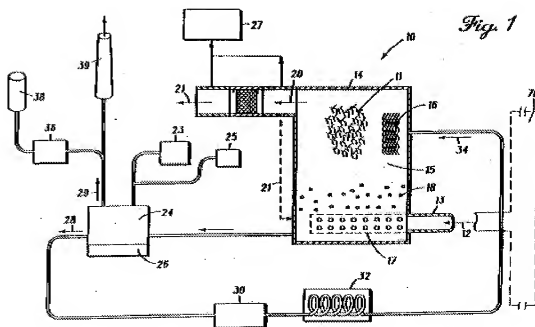
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- (2). **Claims 1, 3, 5-6, 12, 14, 20-22, 24-25, 27, 29** are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (US 5743944A).

As to a method of enriching a component of a gas mixture characterized in that the component flowing in the gas mixture is dissolved in a solvent cooled to below 293 °K in **independent claim 1**, hydrocarbon to be used as solvent in **claim 3**, characterized in that ethanol, toluol, benzene, oliver oil butanol, pentane, methanol and/or acetone are used as solvent

in **claim 5**, wherein ^{129}Xe or ^{13}C being enriched in claim 6, Gross et al (US 5743944A) disclose fluid clathrate system for continuous removal of heavy noble gases from mixtures of lighter gases (Title). An apparatus and method for separation of heavy noble gas in a gas volume. Separation and/or detection of heavy noble gases is an important aspect of a variety of technologies including, for example, collection of helium as a raw material resource (uncontaminated with heavy noble gases), removal of **radioactive xenon** (including ^{129}Xe) and krypton created at nuclear fuel processing facilities, separation of various noble gases from one another (such as recovery of expensive tag gases in nuclear reactor facilities) and detection of heavy noble gases mixed with other gases (Col. 1, line 19-27). It is another object to provide an improved method and apparatus for absorption and controllable release of heavy noble gases which exhibit a highly selective clathrate effect for absorption in the 20 – 22 °C temperature and **even lower (to oil freezing point)** and rapid desorption above about 60 °C. The oil 15 can be any commercially available oil which is a viscous. Combustible, water immiscible liquid soluble in organic solvent such as ether and naphtha and can be animal, vegetable, mineral or synthetic origin (Col. 2, line 51-55). As shown in the Figure below the reservoir 14, gas inlet 12, gas outlet 20.



As to characterized in that the steps for dissolving and degassing the components or the hyper-polarized atomic nuclei in and from the cooled solvent to be repeated at least once in **claim 12**, Gross et al (US 5743944A) disclose the gas stream 20 to be recycled one or more times through reservoir 14 (Col. 3, line 14-16). It would be obvious to have step of dissolving, degassing repeated because of purification. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966).

As to an apparatus for carrying out method of instant claim 1 comprising at least a chamber with means for degassing an enriched component in **claim 14**, Gross et al (US 5743944) disclose the device 24 for mechanical agitation being a commercial blender or heater, or an ultrasonic generator (Col. 3, line 57-60).

As to characterized by a tank for the enriched component connected with the degassing chamber in **claim 18**, as shown in the above Figure of Gross et al, the device 24, and reservoir 14 reads on the limitations as claimed.

As to use of solvents cooled to below 293 °K for enrichment, storage and/or transport of hyper-polarized atomic nuclei or ¹³C in **claim 20**, the disclosure of Gross et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 1 and has been discussed therein.

As to characterized by ethanol, toluol, benzene, olive oil, butanol, pentane, methanol and/or acetone as solvent in **claim 21**, the disclosure of Gross et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 5 and has been discussed therein.

As to characterized by a lipophilic hydrocarbon as solvent in **claim 22**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 3 and has been discussed therein.

As to a solvent in which hyper-polarized atomic nuclei or ¹³C are dissolved, characterized in that the solvent having a temperature of below 293 °K in **claim 24**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claims 1, 2 and has been discussed therein.

As to characterized by ethanol, toluol, benzene, olive oil, butanol, pentane, methanol and/or acetone as solvent in **claim 25**, the disclosure of Gross et al is incorporated herein by

reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 5 and has been discussed therein.

As to characterized by ^{129}Xe as a hyperpolarized noble gas in **claim 27**, the disclosure of Gross et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 6 and has been discussed therein.

As to contrast agents comprising a solvent with hyperpolarized atomic nuclei in claim 29, the disclosure of reference meets the requirements of present claim in terms of types of materials added. It is reasonable to presume that the solution of reference would fulfill the same utility of contrast agent as presently claimed in light of its chemical similarities. The burden is shifted to applicants to establish that the product of present claim is not the same as or obvious as that set forth by the reference.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(3). **Claims 13, 19, 28** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gross et al (US 5743944A).

As to lowering of melting point of solvent occurring by dissolving the component to be enriched in **claims 13 and 28**, in view of substantially identical components, solvent disclosed by Gross et al and by Applicants, it appears that the solution after dissolving the noble gas disclosed by Gross et al would lower the melting point as claimed, Since USPTO does not have proper means for the measurements, the burden now is shifted to Applicants to prove otherwise. *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

As to characterize in that the inner walls of the chambers, tank or other connecting lines comprising especially deuterized monochlorosilane and/or PFA in **claim 19**, it would be obvious to have the inner walls to be made from deuterized monochlorosilane and/or PFA because chosen known materials for suitability renders obvious. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

ALTERNATIVELY, CLAIMS 1-29 ARE REJECTED IN THE FOLLOWING:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(4). **Claims 1-7, 9, 20-29** are rejected under 35 U.S.C. 103(a) as obvious over Pines et al (US 7385395B2).

As to a method of enriching a component of a gas mixture characterized in that the component flowing in the gas mixture is dissolved in a solvent cooled to below 293 °K in **independent claim 1**, hyperpolarized atomic nuclei in **claim 2**, hydrocarbon to be used as

solvent in **claim 3**, characterized in that ethanol, toluol, benzene, oliver oil butanol, pentane, methanol and/or acetone are used as solvent in **claim 5**, wherein ^{129}Xe or ^{13}C being enriched in **claim 6**, deuterized solvent to be used in **claim 7**, a temperature from 10 to 180°K in **claim 9**, Pines et al (US 7385395B2) disclose apparatus for preparing a solution of hyperpolarized noble gas for NMR and MRI analysis (Title). In another embodiment, it provides an apparatus for preparing a solution of hyperpolarized noble gas. The apparatus comprises: a vessel for receiving the fluid; a reservoir for receiving the hyperpolarized noble gas, the reservoir communicating through a 1st shutoff valve with the vessel, the reservoir being shaped to allow the reservoir to be cooled independently of the vessel; a gas inlet port communicating through a 2nd shutoff valve with reservoir. The apparatus can be constructed of any material with the caveats that the material does not speed the relaxation of the hyperpolarized gas and must be capable of withstanding the temperatures necessary to freeze the noble gas (Col. 16, line 20-33). As noted above, the hyperpolarized noble gas is combined with a fluid or **liquid carrier** which is chemically, biologically or materially compatible with the sample to be analyzed **or, in some instance, dissolves as much of the noble gas as possible**. Fluids suitable for use in this methods include, but not limited to, water, saline water, isotonic buffers, lipids, lipids emulsions, organic solvents (e.g., DMSO, **ethanol**, etc) (Col. 9, line 58-65, 21) The term "lipid" refers to any oil or fatty acid derivative. In another embodiment, the noble gas is dissolved in a lipid, lipid solution or lipid emulsion. The oil may be derived from vegetable, mineral or animal sources (col. 10, line 48-51). In preferred embodiments, the noble gas is selected from the group consisting of xenon, helium, neon, krypton and mixtures of these gases. In more preferred embodiments, the noble gas is xenon and in particularly preferred embodiments, the noble gas is either ^{129}Xe or ^{131}Xe . In this method, it is desirable to pre-dissolve the hyperpolarized noble gas in a fluid which can, for example, prolong its relaxation time when the hyperpolarized xenon is in contact with physiological fluids (Col. 9, line 25-33). Fig.8 Time dependence of the hyperpolarized ^{129}Xe NMR signal observed in **benzene** solution after being contacted with hyperpolarized xenon (Col. 5, line 38-40). In a preferred embodiment, the apparatus further comprises a means for freezing the hyperpolarized noble gas. The means to freeze the gas may consist of any means known in the art for attaining temperature sufficiently low to freeze a noble gas (Col. 16, line 63- Col. 17, line 2). The term "contacting" is used herein interchangeably with the following: combined

with, added to, dissolved in, mixed with, flowed over, administered to, injected into, ingested by, etc. The sample can be contacted with hyperpolarized noble gas in a liquid, solid or gas phase.

Prior to contacting the sample with the hyperpolarized noble gas, it may be desirable to freeze the noble gas to preserve the hyper-polarization. It is within the scope of patentee's invention to cool those gases to a temperature above their freezing point (Col. 8, line 38-54).

Therefore, it would be obvious to have the carrier fluid to freeze also above the freezing point of those gases in order to preserve the hyper-polarization and the temperature range would include from 10 to 180 °K. As illustrated in Figures below, the hyper-polarization process as well as the dissolved hyperpolarized noble gas. In Examples, Laser polarization is performed prior to admitting the xenon to the shaker. D₂O is disclosed in Example 1.

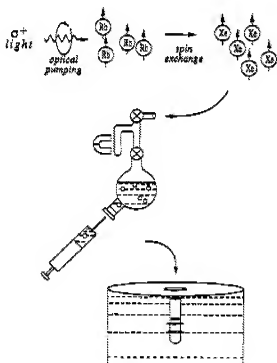


FIG. 1

As to characterize that solvent with an Ostwald coefficient of at least 2 being used for the hyperpolarized atomic nuclei or the component to be enriched in **claim 4**, Pines et al (US 7385395B2) disclose Xenon having a low solubility in saline, with an Ostwald coefficient of only 0.0926 (the standard temperature and pressure volume of xenon dissolved in 1 liter of liquid

at 1 atmosphere of gas pressure; 1atm=101.3 kPa (Col. 21, line 24-27). It would be obvious to have a solvent other than saline with Ostwald coefficient at least 2 to be used to get high solubility of Xenon.

As to during the enrichment, the cooled solvent to be exposed to a maximum magnetic field of about 0.01 to 0.04 Tesla in **claim 8**, Pines et al (US 7385395B2) disclose freezing the noble gas in a magnetic field can preserve the hyper-polarization for a period which is significantly longer than that obtained simply by freezing the gas (Col. 8, line 48-51). In absence of showing the criticality of the records, the optimized magnetic field to be 0.01 to 0.04 Tesla in known process renders prima facie obvious within one of ordinary skills in the art. *In re Boesch, 617 F.2d 272,276,205 USPQ 215,219 (CCPA 1980)*.

As to a lowering of the melting point of the solvent occurring by dissolving the component to be enriched in **claim 13**, in view of the substantially identical solvent, hyper-polarized noble gas in the identical method disclosed by prior art and by Applicants, it appears that the solvent of prior art would have a lower melting point after dissolving the component as claimed. Since USPTO does not have proper means to perform the measurement, the burden now is shifted to Applicants to prove otherwise. *In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977)*.

As to use of solvents cooled to below 293 °K for enrichment, storage and/or transport of hyper-polarized atomic nuclei or ¹³C in **claim 20**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 1 and has been discussed therein.

As to characterized by ethanol, toluol, benzene, olive oil, butanol, pentane, methanol and/or acetone as solvent in **claim 21**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 5 and has been discussed therein.

As to characterized by a lipophilic hydrocarbon as solvent in **claim 22**, characterized by a deuterized solvent in **claim 23**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claims 3,7 and has been discussed therein.

As to a solvent in which hyper-polarized atomic nuclei or ^{13}C are dissolved, characterized in that the solvent having a temperature of below 293 °K in **claim 24**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claims 1, 2 and has been discussed therein.

As to characterized by ethanol, toluol, benzene, olive oil, butanol, pentane, methanol and/or acetone as solvent in **claim 25**, characterized in that the solvent being deuterized in **claim 26**, characterized by ^{129}Xe as a hyperpolarized noble gas in **claim 27**, characterized in that its melting point being lowered by dissolving hyper-polarized atomic nuclei or ^{13}C in **claim 28**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claims 5,7,6,13 and has been discussed therein.

As to contrast agents comprising a solvent with hyper-polarized atomic nuclei in **claim 29**, Pines et al (US 7385395B2) disclose methods of patentee's invention being used for a myriad of diverse applications including, but not limited to new proton contrast agent (Col. 19, line 26-29).

(5). **Claims 10-12, 14-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al (US7385395B2) in view of Gross et al (US 5743944A).

As to degassing to be done following solution of the component or the hyperpolarized atomic nuclei in **claim 10**, Pines et al (US 7385395B2) disclose method comprising: (a) forming a hyper-polarized noble gas intermediate solution by dissolving the hyper-polarized noble gas in a fluid in which the relaxation time of the noble gas is longer than the relaxation time of the noble gas in physiological fluid; and (b) contacting the physiological fluid (sample) with the intermediate solution (col. 4, line 26-31). Pines et al **do not teach** the degassing following the dissolving hyper-polarized noble gas in solvent as claimed.

However, Gross et al (US 5743944A) **teach** fluid clathrate system for continuous removal of heavy noble gases from mixtures of lighter gases (Title). An apparatus and method for separation of heavy noble gas in a gas volume. The oil having absorbed heavy noble gas can be treated by mechanical agitation and/or containment and allow recycling of the oil to the reservoir (Abstract). The oil 15 is then input to means for removal of the heavy noble gas such as a device 24 for mechanically agitating the oil 15 and/or a heated reservoir 26 (Col. 3, line 54-57).

The advantage of degassing of heavy noble gas is for other chemical or radiological analytical device 25 (Col. 3, line 60-65).

Therefore, it would have been obvious to modify the method of Pines et al by degassing the solution which dissolves the noble gas disclosed by Gross et al for the advantages cited herein above.

As to solvent prior to degassing to be guided into chamber for degassing in **claim 11**, Gross et al (US 5743944A) disclose device 24 in Figure 1 which reads on limitations as claimed.

As to characterized in that the steps for dissolving and degassing the components or the hyper-polarized atomic nuclei in and from the cooled solvent to be repeated at least once in **claim 12**, Gross et al (US 5743944A) disclose the gas stream 20 to be recycled one or more times through reservoir 14 (Col. 3, line 14-16). It would be obvious to have step of dissolving, degassing repeated because of purification. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966).

As to an apparatus for carrying out method of instant claim 1 comprising at least a chamber with means for degassing an enriched component in **claim 14**, Gross et al (US 5743944) disclose the device 24 for mechanical agitation being a commercial blender or heater, or an ultrasonic generator (Col. 3, line 57-60).

As to at least a chamber with a cooling apparatus in **claim 15**, the disclosure of Pines et al is incorporated herein by reference, the most subject matter as currently claimed, has been disclosed and discussed for Applicants' instant claim 1.

As to characterized by means for forming a maximum magnetic field of 0.04 T in **claim 16**, the disclosure of Pines et al is incorporated herein by reference, the most subject matters as currently claimed, has been recited in Applicants' instant claim 8 and has been discussed therein.

As to at least a Heimholtz coil and/or a permanent magnet in **claim 17**, Pines et al (US 7385395B2) discloses permanent magnet (Col. 20, line 1).

As to characterized by a tank for the enriched component connected with degassing chamber in **claim 18**, Gross et al (US 5743944) disclose Figure 1, it includes reservoir 14 and device 24 which illustrate the feature as claimed.

As to characterize in that the inner walls of the chambers, tank or other connecting lines comprising especially deuterized monochlorosilane and/or PFA in **claim 19**, it would be obvious

to have the inner walls to be made from deuterized monochlorosilane and/or PFA because chosen known materials for suitability renders obvious. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVES WU whose telephone number is (571)272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Ives Wu

Art Unit: 1797

Date: August 22, 2009

/DUANE SMITH/
Supervisory Patent Examiner, Art Unit 1797